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PATENT  
ATTORNEY DOCKET NO. 10527/003005  
1/29/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Robert N. Hamlin  
Serial No.: 08/692,314  
Filed : August 5, 1996  
Title : METHOD OF MAKING A MULTILAYER ANGIOPLASTY CATHETER  
BALLOON

Art Unit: 1733  
Examiner: Steven Maki

Assistant Commissioner for Patents  
Washington, DC 20231

RECEIVED

JAN 27 1999

STATUS INQUIRY

GROUP 1700

Applicant respectfully inquires as to the status of the above application. The application was filed August 5, 1996 and its last known status was a correspondence dated November 27, 1998 accepting the Power of Attorney.

A stamped, self-addressed envelope is enclosed for your reply to this inquiry. If there are any charges or any credits not covered, please apply them to Deposit Account 06-1050.

Respectfully submitted,

Date: 1/19/99

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Date of Deposit January 19, 1999  
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Kim LaRocca  
Kim LaRocca

Art Unit: 1301

ADVISORY ACTION ATTACHMENT

Applicant argues and the examiner agrees that Levy discloses a process for making a single layer balloon instead of a multi layer balloon. However, Japan '463 motivates one of ordinary skill in the art to modify the process of Levy so that a balloon having at least two layers is made instead of a single layer balloon for the advantage of preventing pinhole formation. Applicant fails to provide any reason or evidence why prevention of pinhole formation is not desired or needed by Levy. Applicant fails to cite any portion which shows that Levy desires pinhole formation and thereby rejects preventing pinhole formation. Examiner's position is that preventing pinhole formation is desirable in Levy because the process of Levy forms a balloon for a catheter which is to be inflated and Japan '463 teaches that a balloon for a catheter which has pinholes is considered by one of ordinary skill in the art to be "inferior".

Applicant argues and the examiner agrees that Japan '463 discloses using a coating process to form two layers instead of coextrusion. However, one of ordinary skill in the art would consider coextrusion and coating to be alternative techniques for forming two layers since Patel and Parker teach using coextrusion to form two layers. Use of coextrusion is not a novel technique

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for forming a tube having two layers. See Parker et al. Use of coextrusion is not a novel technique in the balloon catheter art. See Patel. No unexpected results have been shown for using coextrusion instead of coating. Furthermore, Japan '463 attaches no importance to the use of coating to form the multi layer balloon since Japan '463 expressly states: "Any desired known procedure can be used as the method of forming the balloon part 5." (page 6 of translation).

Applicant's argument that Levy rejects certain polymers is not persuasive. FIRST: Instead of stating that he rejects certain polymers, Levy states: "Although PET homopolymer is the only polymer demonstrated herein, it is to be understood that any high molecular weight polymer that can be extruded into tubing and then drawn and expanded in general accordance with the aforesaid process is operable, for example, a PET copolyester or even a non-polyester, provided the resultant balloon exhibits the desired film properties, such as toughness, flexibility and tensile strength." SECOND: Levy fails to reject using a tube having two or more layers to form a balloon having two or more layers. THIRD: None of applicant's claims require the use of a polymer for the first layer / first tube which is different than that disclosed and suggested by Levy.

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Applicant's argument that Japan '463 teaches away from a relatively high pressure balloon is not persuasive since Japan and Levy are each directed to a balloon for a catheter.

With respect to applicant's arguments regarding Parker, the examiner makes the following comments: FIRST: Applicant's argument that Parker is limited to packaging is incorrect because Parker is directed to coextruded composite film. SECOND: Applicant's argument that Parker's teaching to collapse the film is useless and uncombinable with references relating to inflatable medical balloons is irrelevant since none of the claims require or exclude collapsing the balloon. THIRD AND MORE IMPORTANT: Applicant ignores Parkers' teaching that "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exists in another film."

Applicant argues that it is improper to use two distinct bases (impermeability and adherablity) for the combination. Applicant's argument is off point since the modification of Levy is (1) provide two layers instead of one and (2) use coextrusion to form the two layers. There is no combination of impermeability and adherablity. In contrast, there is motivation to make the modification - this motivation being prevention of pinhole

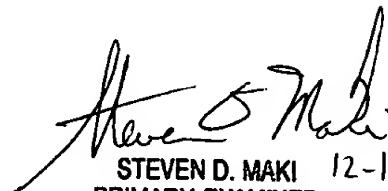
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formation. This motivation is sufficient by itself to establish a prima facie case of obviousness. There is also motivation to make the modification to improve adherability of the balloon of Levy. This means that there is additional and alternative motivation for the proposed modification of Levy; it being noted that applicant fails to explain why reliance must be made on both motivations offered by the prior art to establish a prima facie case.

Trotta et al (filed 11-29-89) is cited of interest for showing a puncture resistant balloon catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1301 is (703) 305-7115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki  
December 16, 1997

  
STEVEN D. MAKI 12-16-97  
PRIMARY EXAMINER  
GROUP 1300